

# CY 2013 CDER New Molecular Entity (NME) & New BLA Calendar Year Approvals

## As of December 31, 2013

This report reflects the data shown as it is identified in the database.

**Selection Criteria:**

**User Response:** Start Date: 1/1/2013 End Date: 12/31/2013

**Sort Order:** Approval Date

**New Molecular Entity Application (NME) Approvals:**

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 022271	NESINA	ALOGLIPTIN	TAKEDA PHARMACEUTICALS USA INC	S	1/25/2013	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 203568	KYNAMRO	MIPOMERSEN SODIUM	GENZYME CORP	S,O	1/29/2013	ADJUNCT TO LIPID-LOWERING MEDICATIONS AND DIET TO REDUCE LOW DENSITY LIPOPROTEIN-CHOLESTEROL (LDL-C), APOLIPOPROTEIN B (APO B), TOTAL CHOLESTEROL (TC), AND NON-HIGH DENSITY LIPOPROTEINCHOLESTEROL (NON-HDL-C) IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH)
NDA 204026	POMALYST	POMALIDOMIDE	CELGENE CORP	S,O	2/8/2013	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING LENALIDOMIDE AND BORTEZOMIB AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY
NDA 203505	OSPHENA	OSPEMIFENE	SHIONOGI INC	S	2/26/2013	TREATMENT OF MODERATE TO SEVERE DYSPAREUNIA, A SYMPTOM OF VULVAR AND VAGINAL ATROPHY, DUE TO MENOPAUSE
NDA 202207	LYMPHOSEEK	TILMANOCEPT	NAVIDEA BIOPHARMACEUTICALS INC	S	3/13/2013	FOR LYMPHATIC MAPPING WITH A HAND-HELD GAMMA COUNTER TO ASSIST IN THE LOCALIZATION OF LYMPH NODES DRAINING A PRIMARY TUMOR SITE IN PATIENTS WITH BREAST CANCER OR MELANOMA

NDA 204781	DOTAREM	GADOTERATE MEGLUMINE	GUERBET LLC	P	3/20/2013	FOR INTRAVENOUS USE WITH MAGNETIC RESONANCE IMAGING (MRI) IN BRAIN, SPINE AND ASSOCIATED TISSUES IN ADULT/PEDIATRIC PATIENTS (FROM 2 YRS OF AGE AND OLDER TO DETECT AND VISUALIZE AREAS WITH DISRUPTION OF THE BLOOD BRAIN BARRIER AND/OR ABNORMAL VASCULARITY
NDA 204063	TECFIDERA	DIMETHYL FUMARATE	BIOGEN IDEC INC	S	3/27/2013	RELAPSING FORMS OF MULTIPLE SCLEROSIS
NDA 204042	INVOKANA	CANAGLIFLOZIN	JANSSEN PHARMACEUTICALS INC	S	3/29/2013	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 204275	BREO ELLIPTA	FLUTICASONE FUROATE AND VILANTEROL TRIFENATATE	GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE	S	5/10/2013	LONG TERM, ONCE DAILY, MAINTENANCE TREATMENT AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AND FOR THE REDUCTION OF COPD EXACERBATIONS
NDA 203971	XOFIGO	RADIUM-223 DICHLORIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	P	5/15/2013	FOR THE TREATMENT OF PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER, SYMPTOMATIC BONE METASTASES AND NO KNOWN VISCERAL METASTATIC DISEASE
NDA 202806	TAFINLAR	DABRAFENIB	GLAXOSMITHKLINE	S,O	5/29/2013	TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E MUTATION
NDA 204114	MEKINIST	TRAMETINIB	GLAXOSMITHKLINE LLC	S,O	5/29/2013	TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATIONS
NDA 201292	GILOTRIF	AFATINIB	BOEHRINGER INGELHEIM	P,O	7/12/2013	FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS HAVE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 (L858R) SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST
NDA 204790	TIVICAY	DOLUTEGRAVIR	VIIV HEALTHCARE CO	P	8/12/2013	ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN ADULTS AND CHILDREN AGED 12 YEARS AND OLDER AND WEIGHING AT LEAST 40 KG
NDA 204447	BRINTELLIX	VORTIOXETINE	TAKEDA PHARMACEUTICALS USA INC	S	9/30/2013	TREATMENT OF MAJOR DEPRESSIVE DISORDER
NDA 022247	DUAVEE	CONJUGATED ESTROGENS/BAZEDOXIFENE	WYETH PHARMACEUTICALS INC WHOLLY OWNED SUB PFIZER INC	S	10/3/2013	IN WOMEN WITH A UTERUS, FOR TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH MENOPAUSE AND PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

NDA 204819	ADEMPAS	RIOCIGUAT	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	10/8/2013	FOR THE TREATMENT OF ADULTS WITH PERSISTENT/RECURRENT CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO GROUP 4, AFTER SURGICAL TREATMENT, OR INOPERABLE CTEPH, TO IMPROVE EXERCISE CAPACITY AND WHO FUNCTIONAL CLASS; AND 2) FOR THE TREATMENT OF ADULTS WITH PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP 1, TO IMPROVE EXERCISE CAPACITY, WHO FUNCTIONAL CLASS AND TO DELAY CLINICAL WORSENING
NDA 204410	OPSUMIT	MACITENTAN	ACTELION PHARMACEUTICALS LTD	S,O	10/18/2013	FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH, WHO GROUP I) TO DELAY DISEASE PROGRESSION.
NDA 203137	VIZAMYL	FLUTEMETAMOL F18	GE HEALTHCARE	S	10/25/2013	FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING OF THE BRAIN TO ESTIMATE B AMYLOID NEURITIC PLAQUE DENSITY IN ADULT PATIENTS WITH COGNITIVE IMPAIRMENT WHO ARE BEING EVALUATED FOR ALZHEIMER'S DISEASE OR OTHER CAUSES OF COGNITIVE DECLINE
NDA 022416	APITOM	ESLICARBAZEPINE ACETATE	SUNOVION PHARMACEUTICALS INC	S	11/8/2013	FOR ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL-ONSET SEIZURES IN PATIENTS WITH EPILEPSY 18 YEARS AND OLDER
NDA 205552	IMBRUVICA	IBRUTINIB	PHARMACYCLICS INC	P,O	11/13/2013	TREATMENT OF PATIENTS WITH MANTLE CELL LYMPHOMA (MCL)
NDA 204153	LUZU	LULICONAZOLE	MEDICIS PHARMACEUTICAL CORP	S	11/14/2013	TOPICAL TREATMENT OF INTERDIGITAL TINEA PEDIS, TINEA CRURIS, AND TINEA CORPORIS CAUSED BY THE ORGANISMS TRICHOPHYTON RUBRUM AND EPIDERMOPHYTON FLOCCOSUM, IN PATIENTS 18 YEARS OF AGE AND OLDER
NDA 205123	OLYSIO	SIMEPREVIR	JANSSEN RESEARCH AND DEVELOPMENT LLC	P	11/22/2013	FOR THE TREATMENT OF CHRONIC HEPATITIS C (CHC) INFECTION, AS A COMPONENT OF A COMBINATION ANTIVIRAL TREATMENT REGIMEN
NDA 204671	SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INC	P	12/6/2013	COMPONENT OF A COMBINATION ANTIVIRAL REGIMEN FOR THE TREATMENT OF CHRONIC HEPATITIS C INFECTION
NDA 203975	ANORO ELLIPTA	UMECLIDINIUM/VILANTEROL	GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE	S	12/18/2013	LONG-TERM, ONCE-DAILY, MAINTENANCE TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

#### New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 125427/0.0	KADCYLA	TRASTUZUMAB EMTANSINE	GENENTECH, INC.	P	2/22/2013	FOR THE TREATMENT OF PATIENTS WITH HER2-POSITIVE, METASTATIC BREAST CANCER WHO PREVIOUSLY RECEIVED TRASTUZUMAB AND A TAXANE, SEPARATELY OR IN COMBINATION.
BLA 125433/0.0	SIMPONI ARIA	GOLIMUMAB	JANSSEN BIOTECH, INC.	S	7/18/2013	FOR TREATMENT OF MODERATE TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS (RA) IN ADULTS IN COMBINATION WITH METHOTREXATE.
BLA 125472/0.0	ACTEMRA	TOCILIZUMAB	GENENTECH, INC.	S	10/21/2013	FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ONE OR MORE DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS (DMARDS)
BLA 125486/0.0	GAZYVA	OBINUTUZUMAB	GENENTECH, INC.	P,O	11/1/2013	FOR THE TREATMENT OF PATIENTS WITH PREVIOUSLY UNTREATED CHRONIC LYMPHOCYTIC LEUKEMIA IN COMBINATION WITH CHLORAMBUCIL

**Review Classification:**

**P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.**

**S - Standard Review - Products that do not qualify for priority review.**

**O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).**